Attorney Docket # 5434-16 Patent

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of
Tom MINER, *et al.*
Serial No.: 10/768,760
Filed: January 29, 2004
For: Intravenous Delivery System

Examiner: Osinski, Bradley J.
Group Art: 4111

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Commissioner for Patents
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APPEAL BRIEF

SIR:

This is an appeal pursuant to 37 C.F.R. § 41.37 from the decision of the Examiner in the above-identified application, as set forth in the Final Office Action dated August 3, 2009, wherein the Examiner finally rejected appellants' claims. The rejected claims are reproduced in the Appendix A attached hereto. A Notice of Appeal was filed on October 5, 2009.

The fee of $540.00 for filing an Appeal Brief pursuant to 37 C.F.R. § 41.20 is submitted herewith. Any additional fees or charges required in connection with this application may be charged to our Patent and Trademark Office Deposit Account No. 03-2412.

REAL PARTY IN INTEREST

The real party in interest is Becton, Dickinson and Company, the assignee of all right, title and interest in and to the subject application.

RELATED APPEALS AND INTERFERENCES

There are no other appeals and/or interferences related to the above-identified application at the present time.

STATUS OF CLAIMS

Claims 1-55 are pending herein. Claims 1-55 are rejected.

STATUS OF AMENDMENTS

There have been no Amendments filed subsequent to the Final Office Action.

SUMMARY OF THE CLAIMED SUBJECT MATTER

The following summary of the invention is offered for the benefit of the Board and is taken from the specification. It is not intended to argue limitations not present in the claims, or to argue for the interpretation of any claim term that is different from, or more narrow than, the broadest reasonable interpretation of such term as it would be understood by one of ordinary skill in the art upon a full and fair reading of the specification.

The invention is directed to a system and method for delivering a solution to a patient through a self-priming intravenous (IV) delivery system, together with components and sub-assemblies of such systems and methods of using such systems.

Independent claims 1 (claims 2-21 and 54 depending therefrom), 22 (claim 23 depending therefrom) and 55 are directed to embodiments of the overall system. Independent claim 24 (claims 25-30 depending therefrom) is directed to an improvement in such a system, namely the location of an opening (as will be described below) in a drip chamber thereof. Independent claims 31 (claims 32-39 depending therefrom) and 40 (claims 41-42 depending therefrom) are directed to embodiments of the drip chamber used in the system. Independent claim 43 (claims 44-48, 52 and

53 depending therefrom) is directed to a solution delivery system. Independent claim 49 (claims 50-51 depending therefrom) is directed to a method of using the system.

Claim 43 includes a "regulating means" which is illustrated in the specification as knurled wheel **25**.

For purposes of this Appeal, appellants argue that the invention as claimed in claims 1-42, and 49-55 is distinct from the prior art based upon the construction of a component of the overall system, namely drip chamber **16.** Drip chamber **16** is a claimed component of the overall system (independent claims 1, 22 and 55), is used in the claimed method (independent claim 49), and is also the subject of its own independent claims (independent claims 31 and 40). It is also a component found in dependent claims 52 and 53 which depend from system claim 43.

Understanding the invention will be simpler if placed in context. The overall system **10** is intended for the IV delivery of a liquid medicament (or "solution") from a container **26** to a patient (not shown). (Fig. 1; page 11. lines 2-6). In use, container **26** dispenses the solution into a drip chamber **16**, from which it enters a patient line **20** from which it is, in turn, dispensed to the patient. (page 11, lines 9-12). Dispensing medicament to a patient in this fashion is well-known, *per se*, and has certain well-known concerns. Among those concerns are the ability to monitor the speed at which the medicament is dispensed (the "flow rate") and the need to ensure that the patient line **20** is free from entrained air bubbles, since permitting entrained air bubbles to be injected into the patient intravenously may lead to the formation of an air bubble ("embolus") in the patient, causing a stroke or death. Both of these concerns are addressed by the inventive drip chamber **16**.

Drip chamber **16** holds the solution after being dispensed from container **26,** and acts as a holding area, where the flow rate of the solution can be monitored by a dispensing professional,

such as a nurse. Drip chambers are usually substantially transparent, to permit the monitoring of the flow rate.

Drip chamber **16** generally starts empty, and must therefore fill up to a desired level ("primed") so that a reservoir **64** forms in the bottom thereof. To allow drip chamber **16** to fill, a regulating means, such as knurled knob **25** is provided, so that the conduit which exits from drip chamber **16** may be closed. The rate of flow of the solution in the system is visually illustrated by the drops of the solution from the top of the chamber to the bottom (illustrated as drops **59** in the Drawings; page 12, lines 5-6). The more drops per second, the faster the flow of solution. Nurses can look at the rate of the drops to determine if the solution is being delivered at an appropriate rate to the patient. It is therefore important that the height of reservoir **64** be set at a level which is neither too high nor too low to allow for proper viewing. It is generally preferred that the height be approximately one-third (1/3) of the overall height of drip chamber **16**. (page 15, lines 12-13).

Those of ordinary skill in the art, therefore, must confront the problem of creating a reservoir of solution in the bottom of the drip chamber that is of a desired height to prevent the formation of air bubbles and yet provide a sufficient distance between the top of the chamber and the surface of the reservoir to allow for viewing of the drip rate. The priming of the system to create a reservoir of the desired height is thus of high importance.

In many prior art systems, the drip chambers are made of a resilient transparent material, to allow for manual priming by, for example, squeezing the drip chamber to force air out of the drip chamber, and then allowing the drip chamber to revert to its original shape, thereby drawing solution into the drip chamber at a faster rate than it will be dispensed, until a reservoir having a desired level of solution forms in the drip chamber. This, however, allows the "over-priming" of the drip chamber, so that the distance between the top of the drip chamber to the top of the reservoir

of solution in the drip chamber may be too small, rendering it difficult to monitor the flow rate. Over-priming is to be avoided, but is a constant risk in manual systems, especially those in which priming may be accomplished by the brute force method of squeezing and releasing a resilient drip chamber.

Another problem with existing IV systems is that when the drip chamber is squeezed to adjust the solution flow rate, the pressurized conditions in the drip chamber may cause the solution to flow into the drip chamber as a narrow stream at high velocity. As the high velocity liquid stream impinges the surface of the reservoir, bubbles become entrapped in the liquid reservoir, thus causing an air-bubble mixture to form. When this occurs, the user, usually a nurse, must perform the time-consuming task of purging the air bubbles from the drip chamber and from the conduit leading to the patient. This typically involves gently tapping the drip chamber and the conduit leading to the patient. If air bubbles are not purged, they may enter the patient and cause an embolism or other harmful effects. (page 5, lines 4-12).

Unwanted air bubbles may also form from a too-rapid filling of IV-solution into the patient conduit in infusion pump systems (*e.g.*, when no drip chamber is present). Such air bubbles form on the inside surface of the conduit and are typically removed by gently tapping the conduit, thereby causing them to dislodge, and then expelling them from an end of the conduit. (page 5, lines 13-16).

These problems are remedied in the system as claimed by the provision of an opening **60** in a side wall **58** of drip chamber **16** (page 14, lines 7-8), which opening **60** is set at a level **X** on side wall **58** that is at the level of solution that provides the desired height of reservoir **64** in drip chamber **16** (page 14, lines 8-9). Opening **60** is covered by a wettable, sealable, vent plug **62** (page 17, lines 4-8), which seals opening **60** when the level of solution reaches vent plug **62** (in opening

60), and provides *self-priming* of the system, *i.e.*, priming to the desired level without intervention by the user. Prior to the solution reaching the level of vent plug **62**, air that is displaced from the entering solution flows through opening **60**, allowing the level of solution to rise to the level of opening **60**. The volume of the solution filling the bottom of drip chamber **16** to form reservoir **64** displaces an equal volume of air in drip chamber **16** at the same rate as the rate of flow of solution into drip chamber **16**.

Once the solution reaches vent plug **62**, however, the liquid solution wets vent plug **62**, causing it to close, thereby sealing opening **60** (page 17, lines 4-8). Once opening **60** is sealed, the volume of air in drip chamber **16** above the height of reservoir **64** (as established by the placement of opening **60**) is fixed, thereby also fixing the height of the reservoir (page 17, lines 11-16). It is important to note that this configuration allows the automatic and precise setting of the height of reservoir **64** to the desired level without intervention from the user, and without the possibility of over-priming (page 17, lines 16-19). After the drip chamber is primed, knurled knob **25** may release the solution into the conduit to prime the conduit before the solution is ultimately dispensed to the patient. The priming of the conduit is described below in relation to the system of claims 43-48.

In the claimed invention, opening **60** is oriented in a direction transverse to the flow of drops **59** of solution in drip chamber **16** (see, *e.g.*, Fig. 1) so that transparent side wall **58** thereof is open to view from all sides and the rate of flow of the drops of solution may, therefore, be monitored without obstruction. The placement and orientation of opening **60** and vent plug **62** therefore permit the self-priming of the system with no intervention by the user, and yet allow for easy viewing of the flow rate from any vantage point.

This combination of features, namely the provision of a wettable vent plug in an opening oriented transverse to the flow of drops of medicament at the desired height of the reservoir, is nowhere shown in the art, and would not be an obvious modification of the art applied by the Examiner.

The invention of claims 43-48, 52 and 53 is directed to a different portion of the overall system, namely a termination end cap which is placed downstream of the drip chamber in the conduit near the patient.

To facilitate formation of reservoir **64** and, specifically, to prevent the medicament from draining into a patient line **20** before reservoir **64** can be formed to a desired depth relative to drip chamber bottom **54**, liquid flow through patient line **20** must be obstructed so that the medicament level will rise in drip chamber **16** at a rate which exceeds the flow of the medicament into the patient line. This can be accomplished by adjustment of roller clamp **24**, such as by manipulating adjustment wheel **25** or, as is contemplated by the preferred embodiment, through termination end vent **72** formed in front wall **73** of termination end cap **70**. Thus, if roller clamp **24** is in its fully opened state, the narrow opening of termination end vent **72** will restrict liquid flow in patient line **20** to a rate which is slower than the rate that the medicament enters drip chamber 16 so that reservoir **64** can form in drip chamber **16** and so that fluid will enter the patient line at a slow rate to prevent the formation of air bubbles in patient line **20**. (page 16, lines 10-22).

Termination end cap **70** includes a termination end vent plug **74** which includes the same or a similar type of wettable, sealable, material of which vent plug **62** is made so that it seals when wetted by the solution. By placing this end plug at the termination end of the patient conduit, the conduit may be purged of any gas bubbles therein before use, and then sealed once the liquid

solution reaches the termination end vent plug. (page 18, lines 1-9). Since any entrapped gas in the conduit may be easily purged therefrom, and then, once the solution wets the termination end vent plug (meaning that the gas has been removed) the end cap is sealed, the conduit, too, may be self-primed without user intervention. This feature is likewise not shown in the art applied by the Examiner.

GROUNDS OF REJECTION TO BE REVIEWED IN APPEAL

The Examiner has rejected claims 1, 6-10, 13, 15-21, 23-26, 28, 30-36, 38-42, 49 and 51 under 35 U.S.C. § 103(a) as obvious over United States Patent No. 6,336,916 (Bormann, *et al.*) in view of United States Patent No. 6,213,986 (Darling, Jr.); claims 2-5, 43-48, 50 and 52-55 under 35 U.S.C. § 103(a) as obvious over Bormann, *et al.* and Darling, Jr. as applied above, further in view of United States Patent No. 4,571,244 (Knighton); claims 11, 12, 14, 27, 29 and 37 under 35 U.S.C. § 103(a) as obvious over Bormann, *et al.* and Darling, Jr. as applied above and further in view of United States Patent No. 6,833,488 (Bucevschi, *et al.*); and claim 22 under 35 U.S.C. § 103(a) as obvious over Bormann, *et al.* and Darling, Jr., as applied above, and further in view of United States Patent No. 4,465,479 (Meisch).

ARGUMENT

This Appeal is the latest installment in the long-running prosecution history of this application, involving four Office Actions, two Notices of Appeal and two separate decisions by Pre-Appeal Review Panels and a constant shifting of the basis for appeal. As will be explained below, applicants maintain that the claimed invention is patentably distinct from the applied art.

Rejection under 35 U.S.C. § 103(a) as obvious over Bormann, et al. *and Darling, Jr.*

1. *Claims 1-42, and 47-55*

The primary reference applied by the Examiner is Bormann, *et al.*, which teaches what the inventors thereof believed to be the best solution to the same problems addressed by appellants: allowing the user to monitor the flow rate of the solution being administered (*see*, col. 1, lines 31-33) and self-priming of the drip chamber without worry of over priming (*see*, col. 1, lines 61-67). The structure of the device taught by Bormann, *et al.* is quite different, however, from that of the invention claimed herein and has drawbacks which are overcome by the invention claimed herein.

Bormann, *et al.* disclose a priming system for use in IV priming systems having a drip chamber (col. 1, lines 28-30) with a housing **14.** Housing **14** receives drops of solution from an inlet **1** into a second chamber **20** to form a reservoir of the solution. While the reservoir forms, gas within housing **14** is permitted to vent through a port **4** having a porous medium **10** therein. Port **4** connects to a vertical gas passageway **5** which extends through the upper portion of housing **14** in a direction parallel to inlet **1** to a port **30** which is positioned above a bottom port **23** of inlet **1.** (See, Fig. 1).

The Examiner applies Bormann, *et al.* as allegedly showing the claimed opening and vent plug (Final Office Action, p. 2, para. 1.a).

However, the element of Bormann, *et al.* that the Examiner likens to the claimed vent plug -- porous medium **10** -- is disposed in a position oriented *parallel* to the flow of drops in the drip chamber (col. 4, lines 51-52: "[M]edium **10** is located in the housing **14**, and has a surface **10a** facing the inlet **1** and a surface **10b** facing the outlet **2.**"). This orientation is perpendicular to that expressly claimed for the opening and vent plug in the instant invention. E*ven though Bormann,* et al. *expressly teach that the ability to observe the rate of flow is important* (*see*, col. 1, lines 52-54),

the positioning of gas passageway **5** in Bormann, *et al.* ***obscures*** the view of the flow of drops through the drip chamber from certain vantages (for example from the right in the Figures of Bormann, *et al.*), limiting the range of view of the flow of drops of solution in the drip chamber. One of ordinary skill in the art reading Bormann, *et al.*, therefore, would conclude that the best way to provide for self-priming would require the user to sacrifice the observability of the flow rate from certain directions (the right in Bormann, *et al.*'s drawings) in order to realize the benefit of self-priming. Furthermore, one of ordinary skill would discern that it is important to vent gas through an outlet at a level which is disposed *above* the level of the reservoir as taught by Bormann, *et al.*

The Examiner has applied Darling, Jr. in an attempt to overcome this shortcoming of Bormann, *et al.* (Final Office Action, page 3, first full paragraph: "Bormann ... does not disclose the opening in the side wall of the drip chamber as forcing the air out in a direction transverse to the drip flow."). The addition of Darling, Jr., however, fails to teach the structure claimed herein.

Darling, Jr. discloses a liquid flow rate control device for use in an IV dispensing system. As in the claimed invention, and as in Bormann, *et al.* (indeed, as in all such systems), Darling, Jr. must provide a mechanism for venting air from the drip chamber while the reservoir is being formed. Darling, Jr. discloses a complicated system for regulating fluid flow while permitting air to leave the drip chamber, a system that is totally unlike that of either the claimed invention or Bormann, *et al.*

Darling, Jr.'s system **10** includes container **12** holding the solution to be dispensed. The solution flows through an inlet member **34** into a first, upper chamber **60**, and then through fluid channels **100** and **102** into a lower chamber **62** (*see*, Fig. 3 of Darling, Jr.). The solution forms a reservoir in the bottom of lower chamber **62** by droplets **64,** causing a float valve **140** to rise until it reaches a predetermined level **84**, at which point valve **140** closes off the bottom of fluid channel

102, allowing the solution to back up into upper chamber **60** causing, in turn, an upper float valve **120** to rise until it blocks off the flow of solution through inlet member **34** into upper chamber **60**. To allow air to flow freely into or out of lower chamber **62**, Darling, Jr. provides a lower vent tube **94** having a micropore element **96** therein to prevent contamination of the solution by the outside air. A similar upper vent tube **90** having a filter **92** therein is provided for upper chamber **60**. Vent tubes **90** and **94** are positioned well above the maximum possible level **84** of the solution so that the filters **92** and **96**, respectively, positioned therein will never be in position to contact the solution, will never be wetted thereby and therefore have no impact on setting the level of the solution in the reservoir formed in the bottom of lower chamber **62**. Vent tubes **90** and **94** are what the Examiner has likened to the claimed vent plug in an opening that is transverse to the flow of drops through the drip chamber.

Appellants concede that these vent tubes **90** and **94** of Darling, Jr. are transverse to the flow of drops through the drip chamber, but their respective filters **92** and **96** *never* get wet and *never* function to seal the flow of air out of the chamber. Moreover, filters **92** and **96** permit air to flow in both directions at all times (depending on what is happening in the chamber) and are located well above the maximum level **84** of the reservoir of solution. The Examiner cannot simply "cherry-pick" the structural feature of Darling, Jr. that the vent may be transverse to the flow of fluid without considering the *entirety* of the reference. M.P.E.P. § 2141.02 (VI) ("A prior art reference must be considered in its entirety, *i.e.*, as a whole, including portions that would lead away from the claimed invention." – emphasis in original).

The filters in Darling, Jr. are not wettable and sealable, as in appellants' claims. They are designed to stay above the reservoir and thereby stay dry, so that they may allow air to pass through, in either direction as necessary. Furthermore, in Darling, Jr., the reservoir is formed by

the action of the float valves **120** and **140**, which is a much more complicated arrangement than in the claimed invention, which uses only the single opening with a wettable material therein. Making a complicated arrangement less complicated is an indication of non-obviousness. *In re Ratti*, 123 U.S.P.Q. 349, 352 (C.C.P.A. 1959).

Furthermore, in both Bormann, *et al.*, and Darling, Jr., the exit of the opening through which the displaced chamber gas passes is located high above the desired level of the reservoir. In Bormann, *et al.*, it is located above the top of the housing and in Darling, Jr. it is located above the exit of inlet member **34**. There is no teaching, suggestion or motivation in the art of record that would lead one of ordinary skill in the art at the time of the invention to move the opening to the side wall of the drip chamber, as claimed, to have a wettable, sealable vent plug therein, as claimed, to thereby define the reservoir height by the placement of the opening, as claimed.

One of ordinary skill at the time of the invention is guided only by the references, and must accept what is in the references, *in re Kotzab*, 56 U.S.P.Q.2d 1313, 1316 (Fed. Cir. 2000). The Examiner has pointed to nothing in the primary combination, or elsewhere in the record, that would teach one of ordinary skill in the art at the time the invention was made to place the opening that vents air to the exterior of the system on the side wall of the drip chamber at the location that corresponds to the desired height of the solution reservoir. This is an important feature of the invention as claimed by appellants herein.

This inventive construction, first proposed by appellants, avoids obstructing the view of the flow rate (unlike Bormann, *et al.*) by orienting the opening in side wall **58** in a direction *transverse* to the flow of the drops **59** at a height equal to the desired height of the reservoir (unlike Darling, Jr.), thereby placing the claimed opening out of the sightline of the user who needs to observe the

flow of drops in the drip chamber from *any angle*. One of ordinary skill in the art would not see any teaching or suggestion in Bormann, *et al.*, Darling, Jr., or the other references of record, to modify the structures taught in the applied art to result in the invention as claimed.

In the Final Office Action (page 12, para. 6.uu), the Examiner argued that the placement and orientation of the claimed opening and vent plug is "both possible and obvious". The Examiner provides no support for this conclusory analysis, and it is a conclusion with which appellants respectfully disagree for the reasons set forth at length above. It is noted, however, that the Examiner does not address the claimed limitation regarding setting the opening at the desired height of the reservoir in his dismissal of the arguments presented by the appellants, and therefore does not meet the arguments presented herein.

For these reasons, it is respectfully submitted that the invention as claimed is not obvious in light of the references applied by the Examiner.

2. *Claims 43-48, 52 and 53*

As to the system of claims 43-48, 52 and 53, Bormann, *et al.* and Darling, Jr. fail to teach the use of a wettable, sealable, end vent plug to permit the automatic priming of the patient conduit line, a shortcoming acknowledged by the Examiner, leading to his addition of the gas debubbler of Knighton to the primary combination (*see, e.g.*, Final Office Action, page 8, para. 2.z). The Examiner then likens the gas debubbler to the claimed termination end vent plug. This is inapposite.

Knighton teaches the use of a double-ended chamber with different filters on its two ends. On one end is a filter **28** that allows gas to pass therethrough but not liquid, and at the other end is a filter **26** that allows liquid to pass therethrough but not gas. With this arrangement, gas in the liquid to be conveyed through the debubbler becomes trapped behind filter **26** and expelled through filter **28**, and therefore does not reach the patient. However, Knighton does not

teach the use of a wettable, sealing vent plug to allow for self-priming, since the two filters **26** and **28** are *never* sealed. It would not be obvious to one of ordinary skill in the art to modify the filters of Knighton to make one of them sealable by wetting, since that would close an end that Knighton teaches should be open. Making this substitution, therefore, flies directly in the face of Knighton's teachings, and contradicts the very purpose of the invention disclosed by Knighton. Thus, changing the structure of Knighton as suggested by the Examiner would not be an obvious modification thereof. In fact, it would be completely contrary thereto.

In the Final Office Action, the Examiner stated that he "does not find any sealing causation in the claim [43]". However, the last three lines of that claim recite: "a termination end vent plug for *preventing the escape of solution through said vent of said termination end cap upon wetting of said termination end vent plug by the solution.*" (emphasis supplied). It is respectfully submitted that this language expressly recites that the termination end vent plug seals when wet, and so the Examiner simply failed to address the claimed limitation. Accordingly, the rejection of independent claim 43 (and the claims dependent therefrom) must also fall as unsupported by the art applied by the Examiner, and inasmuch as the Examiner did not even attempt to meet this argument in the Final Office Action.

Thus, the combination of Bormann, *et al.*, Darling, Jr. and Knighton could not result in the invention as claimed in claim 43 herein.

The additional references applied by the Examiner do not overcome these drawbacks, and were not applied by the examiner to overcome these drawbacks,.. Therefore, they overcome none of the deficiencies of the primary combination.

1. *Claims 2-5, 43-48, 50, 52, 53 and 55*

These claims are directed to the overall system, including both the inventive drip chamber and the inventive termination end cap, and so benefit from both sets of the inventive

contributions discussed above, namely the use of the vent plug in the side of the drip chamber and the termination end cap at the end of the patient conduit. These two features function in combination to permit the self-priming of the entire system without the formation of air bubbles, either in the reservoir in the bottom of the drip chamber or in the patient conduit itself, as would be the case if the system were manually primed. The self-priming which is made possible only in the inventive system saves time and avoids the danger of introducing an air bubble into the patient. Neither feature is shown in the prior art individually, as described above, and so their presence in the system claims renders the overall system claimed in these claims even more clearly patentably distinct from the art applied by the Examiner.

It is believed that no fees or charges are required at this time in connection with the present application. However, if any fees or charges are required at this time, they may be charged to our Patent and Trademark Office Deposit Account No. 03-2412.

Respectfully submitted,
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CLAIMS APPENDIX

1. A self-priming IV-solution delivery system for intravenous delivery of a solution from a container to a patient when the container is disposed at a height above the patient, comprising:

a coupling assembly having an input and an output, said input configured for coupling to the container to provide flow of the solution through the coupling assembly to the output;

a drip chamber having a top wall, a bottom wall, a substantially transparent side wall, an input and an output and coupled, at its input, to said coupling assembly output to receive solution drops formed from the flow of the solution for forming a reservoir defined between said bottom wall and side wall, said drip chamber side wall having an opening located at a height between said top wall and said bottom wall, and a vent plug covering said opening, said vent plug allowing air contained in said drip chamber which becomes displaced upon formation of the reservoir to escape from said drip chamber through said vent plug, said opening being oriented to permit air flow therethrough in a direction transverse to the direction of drip flow of solution from said input to said output of said drip chamber, thereby permitting the substantially unobstructed view of the drip of solution in said drip chamber; and

a patient conduit coupled to said drip chamber output and having a termination end attachable to an intravenous needle of the patient for receiving a flow of solution from the reservoir, said patient conduit having a flow restriction device to restrict the flow of air and liquid in the patient conduit to allow the reservoir to attain a level at least equal to the height of said vent plug while air in the patient conduit is expelled from said termination end, wherein

wetting of said vent plug by the reservoir prevents entry of air through said vent plug to said drip chamber and prevents the exit of solution from said drip chamber through said vent plug.

2. The system of claim 1, wherein said flow restriction device comprises a termination end cap having a vent formed therein, said end cap configured for attachment to said termination end.

3. The system of claim 2, wherein said end cap comprises a termination end vent plug for allowing air present in said patient conduit to pass through said end cap vent and for preventing leakage of solution from said end cap.

4. The system of claim 3, wherein said termination end vent plug comprises a hydrophilic porous material.

5. The system of claim 2, wherein said flow restriction device further comprises a flow restriction device positioned on said patient conduit for selectively closing said patient conduit to isolate the patient from said drip chamber.

6. The system of claim 1, further comprising a flexible conduit coupled between said coupling assembly output and said drip chamber input and having a length for separating a relative distance between said drip chamber and said coupling assembly so that said drip chamber is positioned in close proximity to the patient to provide observation of said drip

chamber, and to provide manipulation of said drip chamber with, at most, minimal disturbance of said coupling assembly.

7. The system of claim 1, wherein a drip orifice is located in said drip chamber top wall for forming the solution drops.

8. The system of claim 1, wherein the height of said side wall opening coincides with a reservoir level occupying approximately 1/3 of the total volume defined in said drip chamber.

9. The system of claim 1, wherein said vent plug comprises an absorbing material and a housing connected to said side wall opening and defining a cavity for receiving a formation of said absorbent material, and wherein said absorbing material comprises a super-absorbent polymer which expands in response to wetting by the reservoir.

10. The system of claim 9, wherein said vent plug further comprises an anti-bacterial agent.

11. The system of claim 1, wherein said vent plug comprises a housing connected to said side wall opening and defining a cavity having a first end in communication with said drip chamber, and a second end in communication with a surrounding atmosphere, said cavity receiving an amount of an absorbing material which expands in response to wetting by the reservoir, said absorbing material comprising a granular super-absorbent polymer, and further

comprising a filter disposed at said first end and a venting membrane disposed at said second end.

12. The system of claim 11, wherein said vent plug further comprises an anti-bacterial agent.

13. The system of claim 1, wherein said vent plug comprises a cannula defining a cavity, and wherein an absorbing material which expands in response to wetting by the reservoir comprises an amount of super-absorbent polymer material disposed in said cavity, said cannula dimensioned for securement within said side wall opening and having a first end in communication with said drip chamber, and a second end in communication with a surrounding atmosphere.

14. The system of claim 1, wherein said vent plug comprises a rigid core of impervious material surrounded by said absorbing material which expands in response to wetting by the reservoir.

15. The system of claim 9, wherein said housing cavity has a trapezoidal cross-section and wherein said formation of said super-absorbent polymer material substantially occupies said housing cavity, said housing further comprising an obstruction positioned at a housing end in communication with said drip chamber for maintaining said formation in said housing cavity.

16. The system of claim 1, wherein said coupling member comprises a piercing member.

17. The system of claim 16, wherein said piercing member defines a closable venting conduit and a liquid conduit.

18. The system of claim 17, wherein said coupling assembly further comprises a funnel portion for directing solution from the container to said drip chamber.

19. The system of claim 18, wherein said coupling assembly further comprises a membrane disposed within said funnel portion for preventing air trapped above said membrane from entering said drip chamber once the container is empty.

20. The system of claim 19, wherein said coupling assembly further comprises an air filter for interfacing an area above said membrane with a surrounding atmosphere to allow air which may be trapped in said coupling member above said membrane to escape to the surrounding atmosphere.

21. The system of claim 1, wherein said coupling member comprises an output end defining a drip orifice for forming the solution drops.

22. A self-priming IV-solution delivery system for intravenous delivery of a solution from a container to a patient when the container is disposed at a height above the patient, comprising:

a coupling assembly having an input and an output, said input configured for coupling to the container to provide flow of the solution through the coupling assembly to the output;

a drip chamber having a top wall, a bottom wall, a substantially transparent side wall, an input and an output and coupled, at its input, to said coupling assembly output to receive solution drops formed from the flow of the solution for forming a reservoir defined between said bottom wall and side wall, said drip chamber side wall having an opening located at a height between said top wall and said bottom wall, and a vent plug covering said opening, said vent plug allowing air contained in said drip chamber which becomes displaced upon formation of the reservoir to escape from said drip chamber through said vent plug, said opening being oriented to permit air flow therethrough in a direction transverse to the direction of drip flow of solution from said input to said output of said drip chamber, thereby permitting the substantially unobstructed view of the drip of solution in said drip chamber;

a patient conduit coupled to said drip chamber output and having a termination end attachable to an intravenous needle of the patient for receiving a flow of solution from the reservoir, said patient conduit having a flow restriction device to restrict the flow of air and liquid in the patient conduit to allow the reservoir to attain a level at least equal to the height of said vent plug while air in the patient conduit is expelled from said termination end, wherein wetting of said vent plug by the reservoir prevents entry of air through said vent plug to said drip chamber and prevents the exit of solution from said drip chamber through said vent plug; and

a splash guard connected to said side wall above said vent plug in an interior of said drip chamber and extending across said vent plug.

23. The system of claim 1, further comprising an outer shield connected to said side wall above said vent plug in an exterior of said drip chamber and extending across said vent plug.

24. In an IV-solution delivery system for intravenous delivery of a solution from a container to a patient when the container is disposed at a height above the patient, having a coupling assembly with an input and an output, said input configured for coupling to the container to provide flow of the solution through the coupling assembly to the output, a drip chamber having a top wall, a bottom wall, a substantially transparent side wall, an input and an output and coupled, at its output, to said coupling assembly to receive solution drops formed from the flow of the solution for forming a reservoir defined between said bottom wall and side wall, and a patient conduit coupled to said drip chamber output and having a termination end attachable to an intravenous needle of the patient for receiving a flow of solution from the reservoir, the improvement providing a self-priming of the solution delivery system and comprising:

an opening formed in said drip chamber side wall at a height between said top wall and said bottom wall, and a vent plug covering said opening, said vent plug comprised of a material for allowing air contained in said drip chamber which becomes displaced upon formation of the reservoir to escape from said drip chamber through said vent plug, said opening being oriented to permit air flow therethrough in a direction transverse to the direction of drip

flow of solution from said input to said output of said drip chamber, thereby permitting the substantially unobstructed view of the drip of solution in said drip chamber; and

said patient conduit having a flow restriction device to restrict the flow of air and liquid in the patient conduit to allow the reservoir to attain a minimum level at least equal to the height of said vent plug while air in the patient conduit is expelled from said termination end, wherein wetting of said vent plug by the reservoir prevents entry of air through said vent plug to said drip chamber and prevents the exit of solution from said drip chamber through said vent plug.

25. The improvement of claim 24, wherein said vent plug comprises a super-absorbent polymer material which swells in response to wetting by the reservoir.

26. The system of claim 25, wherein said vent plug comprises a housing connected to said side wall opening and defining a cavity for receiving a formation of said super-absorbent polymer material.

27. The system of claim 25, wherein said vent plug comprises a housing connected to said side wall opening and defining a cavity having a first end in communication with said drip chamber, and a second end in communication with a surrounding atmosphere, said cavity receiving an amount of said super-absorbent polymer material in a granular form, and further comprising a filter disposed at said first end and a venting membrane disposed at said second end.

28. The system of claim 25, wherein said vent plug comprises a cannula defining a cavity and containing an amount of said super-absorbent polymer material therein, said cannula dimensioned for securement within said side wall opening and having a first end in communication with said drip chamber, and a second end in communication with a surrounding atmosphere.

29. The system of claim 24, wherein said vent plug comprises a rigid core of impervious material surrounded by a layer of super-absorbent polymer material.

30. The system of claim 26, wherein said housing cavity has a trapezoidal cross-section and wherein said formation of super-absorbent polymer material substantially occupies said housing cavity, said housing further comprising an obstruction positioned at a housing end in communication with said drip chamber for maintaining said formation in said housing cavity.

31. A drip chamber for use in a self-priming solution delivery system for intravenous delivery of a solution from a container to a patient, the solution delivery system including a coupling assembly having an input and an output and configured, at its input, for coupling to the container to provide flow of the solution through the coupling assembly output, and a patient conduit line for providing solution from the container to the patient, said drip chamber comprising:

a top wall, a bottom wall, a substantially transparent_side wall, an input and an output and coupled, at its input, to the coupling assembly output to receive solution drops formed

from the flow of the solution for forming a reservoir defined between said bottom wall and side wall, said drip chamber side wall having an opening located at a height between said top wall and said bottom wall, and a vent plug covering said opening, said vent plug allowing air contained in said drip chamber which becomes displaced upon formation of the reservoir to escape from said drip chamber through said vent plug and preventing air from entering said drip chamber through said vent plug and solution from exiting said drip chamber through said vent plug upon wetting of said vent plug by said reservoir, said opening being oriented to permit air flow therethrough in a direction transverse to the direction of drip flow of solution from said input to said output of said drip chamber, thereby permitting the substantially unobstructed view of the drip of solution in said drip chamber.

32. The drip chamber of claim 31, wherein said vent plug comprises an absorbing material disposed in said opening.

33. The drip chamber of claim 31, wherein said vent plug is configured as a band of material having a section comprising an absorbing material, said vent plug being disposed about said drip chamber side wall so that said absorbing material is positioned over said opening for covering said opening with said absorbing material.

34. The drip chamber of claim 33, wherein said absorbing material comprises a super-absorbent polymer which expands in response to wetting by said reservoir.

35. The drip chamber of claim 32, wherein the height of said side wall opening coincides with a reservoir level occupying approximately 1/3 of the total volume defined in said drip chamber.

36. The drip chamber of claim 32, wherein said vent plug comprises a housing connected to said side wall opening and defining a cavity for receiving a formation of said absorbing material, and wherein said absorbing material comprises a super-absorbent polymer which expands in response to wetting by the reservoir.

37. The drip chamber of claim 32, wherein said vent plug comprises a housing connected to said side wall opening and defining a cavity having a first end in communication with said drip chamber, and a second end in communication with a surrounding atmosphere, said cavity receiving an amount of an absorbing material which expands in response to wetting by the reservoir, said absorbing material comprising a granular super-absorbent polymer, said vent plug further comprising a filter disposed at said first end and a venting membrane disposed at said second end.

38. The drip chamber of claim 37, wherein said housing cavity has a trapezoidal cross-section and wherein said formation of said super-absorbent polymer material substantially occupies said housing cavity, said housing further comprising an obstruction positioned at a housing end in communication with said drip chamber for maintaining said formation in said housing cavity.

39. The drip chamber of claim 32, further comprising an outer shield connected to said side wall above said vent plug in an exterior of said drip chamber and extending across said vent plug.

40. A drip chamber for use in a self-priming solution delivery system for intravenous delivery of a solution from a container to a patient, the solution delivery system including a coupling assembly having an input and an output and configured, at its input, for coupling to the container to provide flow of the solution through the coupling assembly output, and a patient conduit line for providing solution from the container to the patient, said drip chamber comprising:

a top wall, a bottom wall, a substantially transparent side wall, an input and an output and coupled, at its input, to the coupling assembly output to receive solution drops formed from the flow of the solution for forming a reservoir defined between said bottom wall and side wall, said drip chamber side wall having a first section formed of a first material impervious to the solution and to air for preventing solution exiting said drip chamber through said side wall first section and for preventing air from exiting and entering said drip chamber through said side wall first section, and a second section located at a height between said top wall and said bottom wall and formed of a second material, said second material being pervious to air when said second material is in a dry state to permit air from inside said chamber to escape to an outside environment, said second material being impervious to air and to the solution when said second material is wetted by said reservoir for preventing solution exiting said drip chamber through said side wall second section and for preventing air from exiting and entering said drip chamber through said side wall second section, said second section being oriented to permit air flow

therethrough in a direction transverse to the direction of drip flow of solution from said input to said output of said drip chamber, thereby permitting the substantially unobstructed view of the drip of solution in said drip chamber.

41. The drip chamber of claim 40, wherein said second material comprises a super-absorbent polymer which expands in response to wetting by said reservoir.

42. The drip chamber of claim 40, wherein the height of said side wall second section coincides with a reservoir level occupying approximately 1/3 of the total volume defined in said drip chamber.

43. A solution delivery system for intravenous delivery of a solution from a container to a patient, comprising:

a coupling assembly having an input and an output, said input configured for coupling to the container to remove solution from the container;

a patient conduit for providing the removed solution to a patient;

means for regulating a flow rate of solution from said coupling assembly to said patient conduit, said patient conduit coupled at one end to said regulating means and having a termination end at the opposite end thereof; and

a termination end cap coupled to said termination end of said patient conduit and having a vent for restricting the flow of solution into said patient conduit and allowing air displaced by the flow of solution through said patient conduit to escape through said termination end, said termination end cap further comprising a termination end vent plug for preventing the

escape of solution through said vent of said termination end cap upon wetting of said termination end vent plug by the solution.

44. The medical delivery system of claim 43, wherein said termination end cap is releasably detachable to said termination end.

45. The medical delivery system of claim 43, wherein said termination end cap is releasably detachable to said termination end by a luer connection.

46. The solution delivery system of claim 43, wherein said termination end vent plug comprises one of a super-absorbent polymer material and a hydrophobic material.

47. The solution delivery system of claim 43, wherein said regulating means comprises a drip chamber.

48. The solution delivery system of claim 43, wherein said regulating means comprises an infusion pump.

49. A method of intravenous delivery of a solution from a container to a patient, comprising the steps of

disposing the container at a height above the patient;

attaching a coupling assembly to said container for providing flow of the solution from the container;

coupling a drip chamber having a bottom wall, a substantially transparent side wall, an input, an output, an opening in the side wall, and a vent plug disposed over said opening, to said coupling assembly to receive solution drops formed from the flow of the solution, said opening being oriented to permit flow therethrough in a direction transverse to the direction of drip flow of solution from said input to said output of said drip chamber, thereby permitting the substantially unobstructed view of the drip of solution in said drip chamber;

connecting a patient conduit to said drip chamber output;

restricting the flow of solution in said patient conduit to a rate below the rate of solution entering said drip chamber to allow a reservoir defined between said bottom wall and side wall to form to a height for wetting said vent plug, said vent plug allowing air contained in said drip chamber which becomes displaced upon formation of the reservoir to escape from said drip chamber through said vent plug;

connecting a termination end of said patient conduit to the patient once the vent plug is wet from the reservoir and air is removed from the patient conduit; and

discontinuing said restriction step upon wetting of said vent plug by said reservoir and removal of air from said patient conduit.

50. The method of claim 49, wherein said restricting step comprises disposing a termination end cap on said termination end, said termination end cap having a vent for allowing air displaced by the flow of solution in said patient conduit to escape through said termination end, said end cap further comprising a termination end vent plug for preventing the escape of solution through said vent upon wetting of said termination end cap plug by the solution.

51. The method of claim 49, wherein said restricting step comprises closing a clamp disposed on said patient conduit.

52. The solution delivery system of claim 47, wherein said drip chamber includes a top wall, a bottom wall, a substantially transparent side wall, an input and an output and is coupled, at its input, to said coupling assembly output to receive solution drops formed from the flow of the solution for forming a reservoir defined between said bottom wall and side wall, said drip chamber side wall having an opening, and a vent plug covering said opening, said vent plug allowing air contained in said drip chamber which becomes displaced upon formation of the reservoir to escape from said drip chamber through said vent plug wherein wetting of said vent plug by the reservoir prevents entry of air through said vent plug to said drip chamber and prevents the exit of solution from said drip chamber through said vent plug, said opening being oriented to permit air flow therethrough in a direction transverse to the direction of drip flow of solution from said input to said output of said drip chamber, thereby permitting the substantially unobstructed view of the drip of solution in said drip chamber.

53. The solution delivery system of claim 52, wherein said termination end cap allows the formation of said reservoir in said drip chamber while simultaneously permitting the escape of air from said conduit through said termination end cap.

54. The solution delivery system of claim 3, wherein said termination end cap allows the formation of said reservoir in said drip chamber while simultaneously permitting the escape of air from said conduit through said termination end cap.

55. A self-priming IV-solution delivery system for intravenous delivery of a solution from a container to a patient when the container is disposed at a height above the patient, the system comprising:

a coupling assembly having an input and an output, said input configured for coupling to the container to provide flow of the solution through said coupling assembly to said output;

a drip chamber having a top wall, a bottom wall, a substantially transparent side wall, an opening in said side wall, an input and an output and coupled, at its input, to said output of said coupling assembly to receive drops of the solution formed from the flow of the solution through said output of said coupling assembly, thereby forming a reservoir defined between said bottom wall and said side wall, said opening being oriented to permit air flow therethrough in a direction transverse to the direction of drip flow of solution from said input to said output of said drip chamber, thereby permitting the substantially unobstructed view of the drip of solution in said drip chamber;

a drip chamber vent plug covering said opening in said drip chamber, said drip chamber vent plug allowing air contained in said drip chamber which becomes displaced upon formation of said reservoir to escape from said drip chamber through said drip chamber vent plug, said drip chamber vent plug being formed at least partly by a wettable material which seals

upon wetting, so that wetting of said drip chamber vent plug prevents entry of air through said drip chamber vent plug into said drip chamber and prevents the exit of solution from said drip chamber through said drip chamber vent plug;

a patient conduit coupled to said drip chamber output and having a termination end attachable to an intravenous needle that may be attached to the patient for receiving a flow of solution from said reservoir and dispensing that flow to the patient;

a termination end cap at said termination end of said patient conduit, said termination end cap including a termination end vent for allowing air entrapped in said patient conduit prior to use to be purged from said patient conduit before the solution is introduced to the patient, said termination end cap having a termination end vent plug for allowing air present in said patient conduit to pass through said termination end vent and for preventing leakage of solution from said termination end cap, said termination end vent plug being formed at least partly by a wettable material which seals upon wetting, so that wetting of said termination end vent plug by the solution flowing through said conduit prevents the exit of solution from said patient conduit through said termination end cap; and

wherein said drip chamber vent plug and said termination end cap cooperate to allow the formation of said reservoir to proceed while purging of said entrapped air from said patient conduit until at least one of said drip chamber vent plug and said termination end vent plug is wetted and thereby sealed.

EVIDENCE APPENDIX

NONE

RELATED PROCEEDINGS APPENDIX

NONE